Remarks

Claims 9 and 23-40 were pending in the subject application. By this Amendment, claims 23 and 27 have been amended and claims 9, 24-26, 28, 30-33, and 35-40 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 23, 27, 29, and 34 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Claim 9 has been rejected under 35 U.S.C. §112, second paragraph, as incomplete for omitting essential steps. The applicants have cancelled claim 9, thereby rendering this rejection moot. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 9 and 23-40 are rejected under 35 U.S.C. §112, first paragraph, as lacking sufficient written description and as new matter. The applicants respectfully submit that the subject specification provides sufficient written description for claims 9 and 23-40. However, by this Amendment, the applicants have cancelled claim 9, and amended claim 23 to lend further clarity to the claimed subject matter.

The Office Action asserts that the subject specification does not provide an adequate written description of homologues or functional fragments of *tatA*, *tatB*, *tatC*, *tatE*, or SEQ ID NOs:11, 12, 13, or 15. The applicants have amended claim 23 to delete reference to homologues or functional fragments.

The Office Action indicates that the subject specification does not provide an adequate written description of a method for screening potential drugs by contacting the recited peptide with the potential drug and determining whether the potential drug inhibits the ability of the peptide to translocate a protein from the bacterial cytoplasm to the periplasm. The applicants respectfully submit that the steps recited in claim 23 are implicit within the disclosure of the subject specification. The fundamental factual inquiry for sufficiency of written description is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. The subject matter of the claim need not be described literally (*i.e.*, using the

same terms or *in haec verba*) in order for the disclosure to satisfy the written description requirement. Information that was well known to persons of ordinary skill in the art need not be included in the application and preferably, is omitted. *In re Buchner*, 18 USPQ 2d 1331 (Fed. Cir. 1991). Furthermore, it is well settled that by disclosing a device that inherently performs a function or has a property, operates according to a theory or has an advantage, the patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. Thus, the application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 178 USPQ 279 (CCPA 1973); and MPEP §2163.07(a).

The role of Tat proteins in translocation was known prior to the filing of the subject application. Moreover, the subject specification teaches that the *tat* system is a *Sec*-independent export pathway that permits translocation of fully folded proteins to the periplasm through a gated pore (page 9, lines 5-9 of the specification) and that the genes and encoded peptides disclosed therein can be used as targets for screening potential drugs (page 2, lines 15-17; page 5, lines 5-7). One of ordinary skill in the art is provided with adequate information regarding the biological activity of the Tat proteins.

The concept underlying the invention is the finding that the Tat proteins are implicated in virulence and that therefore the proteins, or the genes encoding the proteins, are useful targets for antimicrobial therapy. One of ordinary skill in the art reading the whole specification would appreciate that the Tat proteins are useful targets for antimicrobials. Therefore, it is not difficult for one skilled in the art to extend this to evaluating different compounds for their ability to inhibit Tat activity. Once one of ordinary skill in the art is taught that a Tat peptide is an anti-microbial target, standard techniques in the art are immediately envisioned to utilize the peptide in a screen, to identify drugs that alter its natural biological function; it is merely a question of measuring the natural activity of the peptide. A screening assay for antimicrobial drugs merely has to determine whether a drug has the ability to inhibit or alter the natural biological function of a Tat protein. One of ordinary skill in the art can be reasonably expected to know how Tat activity can be determined, in view of the existing knowledge of the Tat export pathway (*e.g.*, Tat proteins and Tat substrates). For example, the Materials and Methods section of the Lee *et al.* publication (page 5873), which was

submitted to the Patent Office with the previous Response on December 15, 2003, indicates that translocation activity of truncated forms of TatA and TatB polypeptides was assessed by measuring trimethyl amine *N*-oxide (TMAO) reductase activity, and cites a 1988 publication (Silvestro *et al.*, *Biochim. Biophys. Acta* 954:1-13) which discloses the methodology. Other Tat substrates could also be utilized. Therefore, there is sufficient information provided within the specification so as to allow the skilled person to carry out a screening assay as recited in the claim.

The applicants respectfully submit that the subject specification reasonably conveys to one of ordinary skill in the art that the inventors were in possession of the claimed invention, and the claimed methods do not represent new matter. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 9 and 23-40 are rejected under 35 U.S.C. §112, first paragraph, as non-enabled by the subject specification. The applicants respectfully submit that the claimed invention is fully enabled by the subject specification.

As indicated above, the applicants have cancelled claims 9, 24-26, 28, 30-33, and 35-40. With regard to claims 23, 27, 29, and 34, once one of ordinary skill in the art is taught that a specific peptide, such as a Tat peptide, is an anti-microbial target, standard techniques in the art are simple to apply in order to utilize the peptide in a screen, to identify drugs that inhibit its natural biological function. Measuring the activity of a peptide may require significant experimentation if its function is not known, but the Tat peptide's function was known and is indicated in the specification. Moreover, assays for measuring the activity of the Tat peptide are well known, as evidenced by the Lee *et al.* publication (page 5873).

The techniques and materials required for carrying out the method of the invention were known and readily available. Thus, one of ordinary skill in the art would not have to resort to undue experimentation to carry out the invention. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine..." *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) (citing *in re Angstadt*, 190 USPQ 214, 217-219 (CCPA 1976)). Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

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In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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Attachment: Petition and Fee for Extension of Time

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